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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,075

03/19/2004

Jeffrey D. Johnson

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38706

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10/18/2007

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EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

10/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/805,075	Applicant(s) JOHNSON ET AL.	
	Examiner Kimberly Chong	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03/19/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 07/27/2007 has been considered. Rejections and/or objections not reiterated from the previous office action 02/22/2007 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 07/27/2007, claims 1-20 and 34-37 are pending in the application. Claims 21 and 34-37 are currently under examination and Applicant has canceled claims 22-33.

Response to Applicant's Arguments

Specification: Sequence Compliance

Applicants have met the requirements for sequence disclosures in the preliminary amendment filed 01/07/2005 and the notice for failure to comply in the Office action sent 02/22/2007 was sent in error.

Re: Claim Rejections - 35 USC § 112

The rejection of claims 21, 23 and 34-37 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention is withdrawn in response to claim amendments filed 07/27/2007.

Re: Claim Rejections - 35 USC § 102

The rejection of claims 21 and 34-36 under 35 U.S.C. 102(b) as being anticipated by Meyers et al. (US 2002/0009779) is obviated in response to claim amendments filed 07/27/2007.

Re: Claim Rejections - 35 USC § 103

The rejection of claims 21, 23 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers et al. (US 20020009779) and Liang et al. (J. of Biological Chemistry, 1990. Vol. 265: 16863-16866) is maintained for the reasons of record filed in the Office action 02/22/2007.

Applicant's arguments filed 07/27/2007 have been fully considered but they are not persuasive. Applicant argues Myers et al. teaches away from the claimed method of identifying an inhibitor for treating or preventing diabetes in favor of treating a proliferative disease because hexokinases are enzymes that phosphorylated sugars and "it is reasonable to expect that the proliferative nature of cancer cells requires up regulation of hexokinases that can process sugars necessary for growth and division, and that an impairment of this ability would have therapeutic utility".

While it is true that Myers et al. teach the polypeptide 50365 (identical to the instantly claimed polypeptide having SEQ ID No. 2) is up-regulated in cancer cells and teach a method of preventing such proliferative disorders by administering an agent that

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inhibits protein expression (see paragraph 0382-0383), this is not the only disorder Meyer et al. teach that can be treated by modulating 50365. As stated in the previous Office action filed 02/22/2007, a method of administering said agent, identified as capable of binding and modulating expression of 50365 polypeptide, to a subject at risk of a disorder or having a disorder associated with increased expression of said 50365 polypeptide and preventing in a subject, wherein the disorder is diabetes (see paragraph 0379-0382 and 0392 and 0068). Therefore, Meyers et al. do not teach away from the claimed method of treating diabetes.

Applicant further argues that Myers et al. does not teach any evidence that 50365 polypeptide is found in the pancreas, namely pancreatic islet cells, as instantly claimed and further argue Myers et al. does not provide any information on the biological role of 50365 in any metabolic disorder and therefore cannot provide any teachings as to the desirability to inhibiting 50365 for treating these disorders.

In response, Meyers et al. was not relied upon to teach contacting a candidate agent that binds 50365 wherein the cell is a pancreatic islet cell. In response to Myers et al. not teaching the desirability of inhibiting 50365 for treating a metabolic disorder, the instant claims are drawn to contacting an agent with a polypeptide having glucose phosphorylating activity and determining a decrease in activity and Myers et al. does in fact teach contacting an agent with a polypeptide i.e. 50365 and determining a decrease of said 50365 wherein the identified agent is capable treating a disorder caused by aberrant expression of said polypeptide, such as diabetes. Thus, Myers et al. does provide teachings of inhibiting 50365 for treating metabolic disorders, such as diabetes.

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Applicant recites similarities between hexokinases and how the state of the art is deficient in supporting the notion that inhibition of hexokinases most similar to hexokinase V can be effective in treating metabolic disorders and further argues that Liang et al. teaches away from monitoring the levels of glucose induced insulin secretion to select an inhibitor of hexokinases similar to hexokinases I-III.

This line of argumentation is not considered convincing and is somewhat confusing. The similarities of the different types of hexokinases in the prior art are irrelevant to the claimed invention and the prior art cited in the 103 rejection of record. The instant claims are drawn to contacting an agent with a polypeptide having glucose phosphorylating activity and determining a decrease in activity and Myers et al. does in fact teach contacting an agent with a polypeptide i.e. 50365, which is identical to the claimed polypeptide having SEQ ID NO. 2. Liang et al. was not relied upon to teach measuring the level of glucose-induced insulin secretion in cells expressing the claimed polypeptide, therefore the level of similarity between the hexokinases has no bearing on the applied prior art reference. Liang et al. was relied upon to teach it would have been obvious to use the method of determining the level of glucose-induced insulin secretion in pancreatic cells in the method taught by Myers et al. Thus, the rejection is maintained for the reasons stated above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner AU 1635

/Sean McGarry/
Primary Examiner
AU 1635